

English translation of
Decision of Rejection

Japanese Patent Application No.: 2004-552275
Your Ref.: 12383680/EJH/DXT
Our Ref.: DC-A0511

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Decision of Rejection
(Translation)

Drafting Date: January 18, 2010
Dispatch Date: January 21, 2010

This patent application is rejected under Rejections 2 and 5 pointed out in the *Notice of Reasons for Rejection* drafted June 17, 2009.

The Applicant's arguments and amendments have been reviewed and examined, but no basis sufficient to overcome the rejection has been found.

Remarks:

- Claim 13

In the *Argument* filed December 21, 2009, the Applicant contends that since amended claim 13 recites that "x is the length of the nucleotide sequence [n] and from 5 to 30," the range of x has been clearly defined, and the scope of the set of oligonucleotides claimed in amended claim 13 is clear. However, it still cannot be understood from the claim language what range of nucleotides is indicated by n. Therefore, claim 13 fails to satisfy the requirement under Japanese Patent Law Section 36(6)(ii).

Accordingly, the rejection pointed out as Rejection 2 in the *Notice of Reasons for Rejection* is sustained.

- Claim 13

In the foregoing *Argument*, the Applicant contends that the range of x is specified in the claim. However, since n is still unspecified, immense variations of nucleotides are encompassed by the claimed set of oligonucleotides, and it is not found that any arbitrary one of such immense variations would have the usefulness described in the specification. Thus, from such immense variations, one skilled in the art would not be able to select any oligonucleotides useful for genotyping a subject, without undue experimentation, thereby defining the scope of the invention claimed in claim 13.

Accordingly, the specification fails to describe the invention of claim 13 in a sufficiently clear and complete manner to enable one skilled in the art to carry out the claimed invention.

Thus, the rejection pointed out as Rejection 5 in the *Notice of Reasons for Rejection* is sustained.

In addition, it should be noted that this application is also rejected for the following reasons:

- Claims 1-18

Cited Documents 1 and 2 and References 4-8, listed below, discloses polymorphisms associated with hearing impairment caused by the connexin 26 mutations shown in Table 1.

Cited Documents 4-8, listed below, disclose the polymorphisms associated with hearing impairment caused by the connexin 26 mutations shown in Table 1.

Cited Documents 9 and 10, listed below, disclose the polymorphisms associated with hearing impairment caused by the pendrin mutations shown in Table 1.

Cited Document 11, listed below, discloses the polymorphism associated with hearing impairment caused by the mitochondrial rRNA mutation shown in Table 1 (A1555G).

Cited Document 12, listed below, discloses the polymorphism associated with hearing impairment caused by one of the usherin mutations shown in Table 1 (2299delG).

As described in Cited Document 3, cited in the foregoing *Notice*, exhaustive detection of polymorphisms using an array is found to have been widely performed before the priority date of the present application.

Taken together, it would be obvious to one skilled in the art to perform exhaustive detection of mutations in the connexin 26, pendrin, mitochondrial 12S rRNA and usherin genes using an array, and the effect of such detection would be well expected by one skill in the art. Furthermore, it is well within the normal creative ability of one skill in the art to design probes comprising the site of a mutation found in the above-mentioned polymorphisms as the probes to be immobilized on the array and to optimize the hybridization conditions. No particular technical features are found in the designing or optimization.

Accordingly, claims 11-18 are not patentable under Japanese Patent Law Section 29(2) since they are obvious to one skilled in the art in view of Cited Documents 1-3 and References 4-12.

List of References

4. Arch. Otolaryngol. Head Neck Surg. (2001) Vol. 127, pp. 1037-1042
5. Genetic Testing (2001) Vol. 5, No. 2, pp.147-148

6. Int. J. Pediatr. Otorhinolaryng. (Sept., 2002) Vol. 65, pp.101-108
 7. WO 02/50305
 8. Laryngoscope (Jul., 2002) Vol. 112, pp.1159-1162
 9. Hum. Mol. Genet. (2000) Vol. 9, No. 11, pp.1709-1715
 10. Clin.Endocrinol. (2000) Vol.52, pp.279-285
 11. Pharmacogenetics (1995) Vol. 5, pp.165-172
 12. Am. J. Hum. Genet. (2001) Vol. 69, pp.228-234
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If the Applicant dissatisfied with the above decisions, he/she may file an appeal with the Commissioner of the JPO within three months (four months for residents abroad) from the dispatch date of this *Decision* (Japanese Patent Law Section 121(1)).

Instructions in accordance with Administrative Case Litigation Law. Article 46(2)

The Applicant may only file an action for revocation of the decision given on the appeal filed against this decision (Japanese Patent Law Section 178(6)).